

qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(ii) *Specific health claims.* (A) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a malt beverage label. If FDA determines that the use of such a labeling claim is a drug claim that is not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, TTB will not approve the use of that specific health claim on a malt beverage label.

(B) TTB will approve the use of a specific health claim on a malt beverage label only if the claim is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(iii) *Health-related directional statements.* A statement that directs consumers to a third party or other source for information regarding the effects on health of malt beverage or alcohol consumption is presumed misleading unless it—

(A) Directs consumers in a neutral or other non-misleading manner to a third party or other source for balanced information regarding the effects on health of malt beverage or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(2) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

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Subpart D—Requirements for Withdrawal of Imported Malt Beverages From Customs Custody

§ 7.30 Application.

Sections 7.30 and 7.31 shall apply to withdrawals of malt beverages from customs custody only in the event that the laws or regulations of the State in which such malt beverages are withdrawn for consumption require that all

malt beverages sold or otherwise disposed of in such State be labeled in conformity with the requirements of §§ 7.20 through 7.29.

§ 7.31 Label approval and release.

(a) *Certificate of label approval.* No imported malt beverages in containers shall be released from Customs custody for consumption unless there is deposited with the appropriate Customs officer at the port of entry the original or a photostatic copy of an approved certificate of label approval, ATF Form 5100.31.

(b) *Release.* If the original or photostatic copy of ATF Form 5100.31 has been approved, the brand or lot of imported malt beverages bearing labels identical with those shown thereon may be released from U.S. Customs custody.

(c) *Relabeling.* Imported malt beverages in U.S. Customs custody which are not labeled in conformity with certificates of label approval issued by the appropriate ATF officer must be relabeled, prior to release, under the supervision and direction of the U.S. Customs officers of the port at which the malt beverages are located.

(d) *Cross reference.* For procedures regarding the issuance, denial, and revocation of certificates of label approval, as well as appeal procedures, see part 13 of this chapter.

[T.D. ATF-66, 45 FR 40552, June 13, 1980, as amended by T.D. ATF-94, 46 FR 55097, Nov. 6, 1981; T.D. ATF-242, 51 FR 39525, Oct. 29, 1986; T.D. ATF-359, 59 FR 42160, Aug. 17, 1994; T.D. ATF-406, 64 FR 2129, Jan. 13, 1999]

Subpart E—Requirements for Approval of Labels of Malt Beverages Domestically Bottled or Packed

§ 7.40 Application.

Sections 7.40 through 7.42 shall apply only to persons bottling or packing malt beverages (other than malt beverages in customs custody) for shipment, or delivery for sale or shipment, into a State, the laws or regulations of which require that all malt beverages sold or otherwise disposed of in such State be labeled in conformity with the requirements of §§ 7.20 through 7.29.